

08/779,457 01/07/97 CARTER

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EXAMINER

HM12/1121

GINGER R. DREGER
KNOBBE, MARTENS, OLSON & BEAR, LLP
620 NEWPORT CENTER DRIVE
SIXTEENTH FLOOR
NEWPORT BEACH CA 92660

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on Response of 8-28-00
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-33 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-33 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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1. Part III: Detailed Office Action

2. FORMAL MATTERS

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objections, rejections, and/or concerns not herein restated have been withdrawn.

3. Applicant's arguments filed 8-28-00 as Paper No 27 have been fully considered but they are not persuasive. See the arguments following the rejection below.

Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.

4. Rejections Over Prior Art:

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snodgrass et al. ('080).

This newly issued patent to Snodgrass et al ('080) is a divisional of S.N. 08/355888, which matured into patent number 5,763,211. Therefore, the disclosure of this new divisional patent is the same as the parent, which disclosure has been set forth in the previous office of Snodgrass et al ('211). In addition to those teachings, this divisional patent 6,005,080 to Snodgrass et al claims antibodies to the hematopoietin receptor, which has a WSX motif (see the claims, col 6 and 12-13). The claimed antibodies are stated to specifically bind to the receptor of Seq ID 8, which SEQ ID comprises amino acids 1-960. The patent claims further state that the antibody recognizes structurally unique site on the receptor.

At the time of filing or the effective filing date of the patent to Snodgrass et al, the patentee was aware of the fact that their receptor was a hematopoietin receptor and that there were multiple specie forms/variant forms of this receptor. But what was not known to the patentee was that their receptor was the Ob/leptin receptor. However, despite the name by which the receptor protein is referred to (e.g. HU-B1.219, or hematopoietin receptor, or OB-Receptor, or Leptin receptor) the fact remains that the receptor is the same, with the exception of the

various variant forms, irrespective of the different names by which it is referred. The patent teaches at col 12-13 that antibodies to the receptor can be prepared, and that neutralizing antibodies can also be prepared. While the patent does not expressly state that the non-neutralizing antibodies are agonist antibodies, one skilled in the art would more than reasonably expect that these antibody would be an agonist antibody just based on the meaning of agonist and applicants meaning for the different antibodies that can be prepared against the receptor. The instant claims state that the antibody binds the extracellular domain of WSX, and this appears to be met by the claims which states that the antibody bind to the receptor having amino acids 3-887, since the extracellular domain is within these specified residues. The final limitation of claim 1 is that the antibody to the receptor decreases body weight. As stated above, the examiner concedes that the patentee was not aware of the fact that their receptor was the leptin receptor and that antibodies to such could also be used to modulate weight. Despite such, the claims would still have been prima facie obvious from the prior art, despite the presence of the functional language, because the physical characteristic of the claimed antibody appears to be the same or substantially the same as that of the patent. Therefore, the prior art would have rendered the claims prima facie obvious for all of the reasons stated above.

Although the art for the obviousness rejection has changed, the rejection is substantially the same. Applicant's arguments have been considered, even as it applies to the newly issue Snodgrass et al patent, but are not deemed to be persuasive. At the middle of page 2 of the response, applicants states the they have inferred from my previous office action that my statements about the functional limitation implied that "the anti-hematopoietin receptor antibodies, the making of which is suggested (but not specifically disclosed) by Snodgrass et al. would inherently have the functional properties of the antibodies claimed in the present application." The above set forth rejections appear to address this line of argument. The other argument is that nonobviousness and novelty are different and distinct requirements. This has been considered, but it not clearly understood with regard to the rejection, because the prior rejection

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did not appear to equate these two. Also argued is that any potential teaching of Snodgrass et al for making agonist antibodies is merely an invitation to make such. Although the prior art does not expressly make antibodies, whether agonist, antagonist or otherwise, the teachings that span col 12-13 constitute guidance that would have rendered obvious antibodies that meet the claim limitations. Also argued is that the making of agonist antibodies would not have been routine for making antibodies that mimic any biological property of a native ligand, however, most contrary to this position, the making of such antibodies was very well known at the time of the patent and constituted routine skill in the art-consistent with the teachings at col 12-13. However, it is further pointed out that the instant claims are not sufficiently specific in setting forth physical and/or functional characteristic, nor the recitation of binding affinity or binding specificity to distinguish from the antibodies of the patent. Accordingly, the claims are prima facie obvious from the patentee.

At this time, it is believed that all pertinent arguments have been answered.

5. Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1647, whose telephone number is (703) 308-4232**. Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

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Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.



GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800